

## **REMARKS**

Support for the amendments to claim 1 can be found, for example, at page 5, lines 12-19, lines 30-31 and paragraph 4. Further support can be found on page 9 at lines 16-21, on page 11 at lines 4 to 14 and on page 12 at lines 6-8 where electron microscope examinations of the mineralized layer are disclosed. Amended claim 1 clarifies that the coating is *adhered to* the implant surface. Based on the many descriptions of the microscopic examinations found in applicants' specification, it would be clear to one skilled in the art that each layer of the bone analogous coating comprises a network of mineralized collagen fibrils, amorphous calcium phosphate clusters and crystalline hydroxyapatite.

### **Rejections under 35 U.S.C. §102(b)**

Applicants' claims 1-3, 5, 10-16, 18-19, 21, 23 and 27 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Worch et al (US 6,524,718). These rejections are rendered moot by amending the claims to clarify that the layers are adhered to the implant surface and further incorporating features of mineralized collagen.

Worch teaches an organic and/or inorganic component that becomes incorporated into the metallic oxide phase such that the polyphase oxide coating compares with an alloy (see column 2, lines 55-59 and Examples 1 and 2). The coatings of Worch are embedded in the oxide surface of the implant. Worch does not teach or suggest a mineralized collagen layer with a bone analogous structure in the form of layers *adhered to* a metallic implant surface.

Claims 1-4, 10-16, 18-19, 21, 23 and 27 are rejected under 35 USC 102(b) as allegedly being anticipated by Shirkanzadeh (US 5,205,921). These rejections are rendered moot by amendments to claim 1.

At page 7 of the Office Action the Examiner points to the Merriam-Webster Dictionary definition of "Mineralize". Generally speaking, terms are given their plain meaning, unless the term has a particular meaning within the specification and if the inventor has chosen to be his/her own lexicographer and give the term a special meaning. Applicants meaning of the term mineralize can easily be determined by examining the specification in which the use of the term is in relation to the field of bio-mineralization. Shirkanzadeh does not disclose an implant having a collagen matrix mineralized with a calcium phosphate phase in accordance with applicants' invention.

Furthermore, the particle sizes of Shirkanzadeh (5-10 $\mu$ m) are too large to promote formation of a network of mineralized collagen fibrils, amorphous calcium phosphate clusters and crystalline hydroxyapatite interconnected layers. This can be seen in previously submitted Figure 1 (attached). Thus, Shirkanzadeh is particularly silent regarding a bone analogous coating wherein the mineralized collagen matrix is constructed in the form of layers, and each layer comprises a network of mineralized collagen fibrils, amorphous calcium phosphate clusters and crystalline hydroxyapatite.

In view of the above remarks, withdrawal of the rejections under 35 USC §102(b) is respectfully requested.

#### **Rejections under 35 U.S.C. §103(a)**

Claims 6 and 26 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Shirkanzedah (US 5,205,921) in view of Sauk et al (US 4,780,450) and claims 5, 7-8, 17 and 24-25 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Shirkanzedah (US 5,205,921) in view of Kwan. These rejections are rendered moot by amendments to claim 1.

Finally, claims 1-3, 5, 7-8, 10-19, 23 and 27 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Rhee (5,543,441).

At page 13 of the Office Action the Examiner again relies on the Merriam Webster

Dictionary definition of mineralize. As noted above, applicants meaning of the term mineralize can easily be determined by examining the specification in which the use of the term is in relation to the field of bio-mineralization. Applicants have previously discussed the structurally distinguishing physical characteristics of applicants' bone analogous coating, as examined by electron microscopic.

Rhee teaches implants coated with a collagen-polymer conjugate. The collagen, preferably reconstituted atelopeptide collagen, is chemically bonded to a synthetic hydrophilic polymer, preferably polyethylene glycol, to form a collagen-polymer conjugate. The coatings of Rhee are functionalized collagen-polymer-conjugates and not collagen matrix mineralized with a calcium phosphate. There is nothing within Rhee that would lead one skilled in the art to arrive at a coating comprising a network of interconnected layers of mineralized collagen fibrils, amorphous calcium phosphate clusters and crystalline hydroxyapatite.

Thus, Worch, Shirkanzadeh, Sauk, Kwan and Rhee do not teach a coated metallic implant having a collagen matrix mineralized with a calcium phosphate phase. They are particularly silent regarding a bone analogous coating comprises a mineralized collagen matrix constructed in the form of layers wherein each layer comprises a network of mineralized collagen fibrils, amorphous calcium phosphate clusters and crystalline hydroxyapatite.

Therefore, it is respectfully requested that the rejections under 35 U.S.C. §103 should be withdrawn.

In view of the amendments and above remarks, favorable consideration is courteously requested. However, if there is any remaining issue(s) which can be expeditiously resolved by a telephone conference, the Examiner is courteously requested to telephone the undersigned at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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